EXHIBIT A

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF SUFFOLK

IN RE OPIOID LITIGATION	**Index No. 400000/2017** **Motion Sequence No. __** **Hon. Jerry Garguilo**

THIS DOCUMENT RELATES TO:

COUNTY OF SUFFOLK, Plaintiff -against- PURDUE PHARMA L.P. *et al.*, Defendants.	Index No. 400001/2017 Hon. Jerry Garguilo
COUNTY OF NASSAU, Plaintiff -against- PURDUE PHARMA L.P. *et al.*, Defendants.	Index No. 400008/2017 Hon. Jerry Garguilo
THE PEOPLE OF THE STATE OF NEW YORK, BY LETITIA JAMES, ATTORNEY GENERAL OF THE STATE OF NEW YORK, Plaintiff, -against- PURDUE PHARMA L.P., *et al.*, Defendants	Index No.: 400016/2018 Hon. Jerry Garguilo

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT CONCERNING DEFENDANTS' STATUTORY AND REGULATORY DUTIES

January 14, 2020

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Administrative Decisions

Federal Statutes, Rules, and Regulations

State Statutes, Rules, and Regulations

Other Authorities

INTRODUCTION

All of the Defendants – Manufacturers, Distributor, and Pharmacy Chains -- are subject to regulation under the federal Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.*, and the New York Controlled Substances Act ("NYCSA"). Plaintiffs have asserted several claims for which the Defendants' compliance with the CSA and the NYCSA is relevant, including Plaintiffs' public nuisance claim. In particular, Defendants' violation of various statutory and regulatory norms is relevant to establishing that their conduct created and constitutes a public nuisance. The parties do not agree, however, on what the CSA and the NYCSA require Defendants acting as manufacturers and distributors to do with respect to "suspicious orders." Nor do the parties agree on what the CSA requires of pharmacies and their corporate parents with respect to prescriptions that raise "red flags" of diversion. Thus, before the Court can adjudicate any factual disputes as to Defendants' compliance with their statutory and regulatory obligations (or even determine whether there are such factual disputes), it will be necessary to determine what the statutes and regulations require. Through this motion, Plaintiffs seek summary adjudication of those legal questions.

The CSA and the NYCSA both require manufacturers and distributors of opioids to maintain "effective controls against diversion." 21 U.S.C. § 823(a)(1), (b)(1); Pub. Health Law § 3312. Pursuant to regulations adopted by the federal Drug Enforcement Administration ("DEA"), the agency charged with administration of the CSA, the maintenance of such controls requires registrants to design and operate a system for identifying and reporting suspicious orders. *See* 21 C.F.R. § 1301.71(a). One of the disputes at issue on this motion concerns the further duty to refrain from shipping suspicious orders until the registrant can determine, through investigation and due diligence, that the order is not likely to be diverted. As described below, the DEA has construed the CSA to impose this duty because a registrant's controls against diversion will not be effective if orders identified and reported as suspicious are nonetheless shipped before it can be determined that they are unlikely to be diverted. *See Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (Dep't of Justice July 3, 2007). Congress has recently ratified this construction. *See* Public Law 115-271,

§ 3272. The federal MDL court adopted this construction as well. *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019) (attached for the Court's convenience as Exhibit F to the Affirmation of Andrea Bierstein ("Bierstein Aff.")..

The other issue pertains to the claims by Nassau and Suffolk Counties (the "Counties") against the Pharmacy Chains, which act in two separate capacities with respect to opioids.[1] First, Pharmacy Chains act as wholesale distributors, distributing opioids to their own retail stores. In that capacity, the Pharmacy Chains have precisely the same duties as any other distributor. But Pharmacy Chains also dispense opioids at retail. In that capacity, the Pharmacy Chains must ensure that the prescriptions dispensed at their stores are dispensed pursuant to a legitimate prescription, and must not fill prescriptions without resolving "red flags" of diversion. Importantly, these duties are not limited to individual pharmacists or particular retail stores, or to the company that holds the CSA registration for dispensing controlled substances. Rather, the corporate parent of the retail pharmacy stores is obliged to ensure that prescriptions are dispensed only pursuant to valid and medically legitimate prescriptions.

At trial, Plaintiffs will demonstrate that the Defendants failed to meet their statutory and regulatory duties, and that their failure was a contributing cause of the opioid epidemic on Long Island, in New York State, and across the nation. On this motion, Plaintiffs ask that the Court issue an order clearly delineating what those statutory and regulatory duties are, in order to clarify the issues for trial.

LEGAL STANDARD

CPLR 3212(e) provides that "summary judgment may be granted as to one or more causes of action, or part thereof, in favor of any one or more parties, to the extent warranted, on such terms as may be just." CPLR 3212(b) provides "[t]he motion shall be granted if … the cause of action [is] established sufficiently to warrant the court as a matter of law in directing judgment in favor of any party." *See Gilbert Frank Corp. v. Federal Ins. Co.*, 70 N.Y.2d 966 (1988); *Friends of Animals v Associated Fur Mfrs.*, 46 N.Y.2d 1065 (1979).

[1] The State does not join in the arguments made against the Pharmacy Chains, who are Defendants only in the Counties' actions.

In order to prevail on a motion for summary judgment, the proponent must make a *prima facie* showing of entitlement to judgment as a matter of law by providing sufficient evidence to eliminate any material issues of fact. *Winegrad v. N.Y. Univ. Med. Ctr.*, 64 N.Y.2d 851, 853 (1985). Once the movant's initial burden is met, it becomes incumbent upon the party opposing the motion to "produce evidentiary proof in admissible form sufficient to require a trial of material questions of fact upon which the opposing claim rests." *Gilbert Frank Corp.*, 70 N.Y.2d at 967.

ARGUMENT

I. THE CSA AND NYCSA DUTY TO "MAINTAIN EFFECTIVE CONTROLS AGAINST DIVERSION" REQUIRE MANUFACTURERS AND DISTRIBUTORS TO IDENTIFY AND REPORT SUSPICIOUS ORDERS AND TO HALT SHIPMENTS OF SUCH ORDERS PENDING INVESTIGATION

A. The Federal Controlled Substances Act Requires Manufacturers and Distributors to Halt Shipments of Suspicious Orders Pending Investigation

The CSA sets forth as a primary factor in the grant of a registration to manufacture or distribute controlled substances the "maintenance of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). This duty has remained substantially unchanged since the enactment of the CSA in 1970. This duty is further codified by the DEA at 21 C.F.R. § 1301.71(a), which provides that "[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." This DEA requirement has remained substantially unchanged since its adoption by the DEA in 1971. *See Notice of Proposed Rulemaking: Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970,* 36 Fed. Reg. 4928 (Dep't of Justice Mar. 13, 1971); *Final Rule: Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970,* 36 Fed. Reg. 7776 (Dep't of Justice Apr. 24, 1971).

The duty to maintain effective controls against diversion is not merely a technical requirement. The regulatory scheme established by the CSA does not rely on the DEA to police shipments of controlled substances in the first instance, but rather it enlists registrants to do so and requires them to assume that task, in exchange for the privilege of dealing in dangerous narcotic drugs. *See Southwood*

Pharmaceutical, 72 FR 36487-01, 36504, 2007 WL 1886484 (the DEA cannot all by itself "protect the American people from [the] extraordinary threat to public health and safety" posed by prescription narcotics; it "must rely on registrants to fulfill their obligation under the Act to ensure that they do not supply controlled substances to entities which act as pushers."). Moreover, the legislative history of the CSA shows that one of the fundamental purposes of the statute is to protect society from the dangers that controlled substances pose to the safety of communities. H.R. Rep. 91-1444, 4574, 4601-2 (1970). As the DEA noted in revoking the registration of a distributor in *Southwood Pharmaceuticals*, "[r]espondent's distribution of 44 million dosage units of hydrocodone which were likely diverted caused extraordinary harm to the public health and safety." 72 FR 36487-01, 36503, 2007 WL 1886484. Indeed, the DEA characterized the recipients of the suspicious orders as "drug pushers operating under the patina of legitimate authority" and found that "[c]utting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety." *Id.* at 36504.

The DEA has construed the CSA to require registrants to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty"). *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration,* 861 F.3d 206, 212-213 (D.C. Cir. 2017);[2] *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484. The first two of these duties, the identification and reporting requirements, are explicitly set forth at 21 C.F.R. § 1301.74, which provides that a registrant "shall design and operate a system to disclose to the registrant suspicious orders of controlled substances" and that the registrant "shall inform the Field Division Office of the Administration in his area of suspicious orders *when discovered by the registrant*."

[2] In *Masters Pharmaceutical*, the court described this as a "shipping duty." Because the duty as described by the *Masters Pharmaceutical* court and by the DEA clearly requires registrants to refrain from shipping, Plaintiffs here refer to it as the "no-shipping duty" in the interest of clarity.

(Emphasis added.) The regulation defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*

The no-shipping duty, while not set forth in the same express terms, is nonetheless inherent in the over-arching duty to maintain effective controls against diversion. *See Masters Pharmaceutical,* 861 F.3d 212-13. Indeed, in the federal MDL, the district court held not only that Manufacturers and Distributors are under a duty "not to ship suspicious orders," *see In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, but further held that:

> [G]iven the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

Id. at *9, Bierstein Aff., Ex. F. Thus, the MDL court granted the federal bellwether plaintiffs' motion for partial summary judgment with respect to the CSA duties of the manufacturers and distributors, the federal analog of this motion.

This Court should follow the MDL court and reach the same conclusion. The district court's conclusion is well-supported by the DEA's long recognition of the duty *not to ship* suspicious orders until they have been cleared through investigation. *See Masters Pharmaceutical,* 861 F.3d at 212-13 ("Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."); *Southwood Pharmaceuticals,* FR 36487-01, 36500, 2007 WL 1886484; *see also* Affirmation of Andrea Bierstein ("Bierstein Aff."), Exhibit A, DEA Rule 30(b)(6) Depo. (Prevoznik), Vol. 2, p. 771 (April 18, 2019) ("Q.: Does the DEA take the position that a registrant of controlled substances has a duty to block shipments of suspicious orders? A: Yes.").[3] As explained by the DEA in *Southwood Pharmaceuticals,* the no-shipping duty follows directly from the

[3] The DEA produced Thomas Prevosnik as a Rule 30(b)(6) witness in the MDL proceedings. Mr. Prevosnik's testimony thus represents the official position of the DEA.

statutory requirement that a registrant maintain effective controls against diversion. In *Southwood Pharmaceuticals,* the DEA revoked the registration of a distributor based primarily on the failure to maintain such controls. The DEA found that not only had Southwood failed to report suspicious orders, but also that it had failed to perform proper due diligence with respect to its customers, and that it had continued to ship to certain customers, even though the orders it shipped met the criteria to be considered "suspicious." 72 FR 36487-01, 36498-99. Indeed, the DEA found it "especially appalling" that, in light of the information available to it indicating that certain pharmacies to which it was shipping hydrocodone were engaging in diversion, Southwood "did not immediately stop distributing hydrocodone to any of the pharmacies." *Id.* at 36500. The DEA noted "the threat to public safety posed by the diversion of controlled substances" and revoked Southwood's license, effective immediately, finding that "continued registration constituted an imminent danger to public health and safety." *Id.* at 26504. Thus, Southwood's violation of the no-shipping requirement was one of the primary reasons its registration was revoked.

The DEA further and unequivocally removed any doubt about the existence of the no-shipping duty in letters it sent to opioid distributors in 2006 and 2007. In a September 26, 2006 letter, the DEA reminded distributors that in addition to an obligation to report suspicious orders, they had a "statutory responsibility to exercise due diligence to avoid *filling* suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels." *See* Bierstein Aff., Exhibit B (emphasis added). (Notably, this letter was sent approximately ten months before the administrative decision revoking Southwood Pharmaceuticals's registration.) In December, 2007, the DEA once again reminded distributors that

> their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders *prior to completing a sale* to determine whether the controlled substances are likely to be diverted from legitimate channels."

See Bierstein Aff., Exhibit C (emphasis added).

As the DEA letters make clear, and as explained in *Southwood Pharmaceutical*, the no-shipping duty is nothing more than an implementation of the basic duty to "maintain effective controls against

diversion." *See* FR 36487-01, 36498-502, 2007 WL 1886484. As the MDL court found, there can be no "effective controls against diversion" if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. Thus, the no-shipping duty is not a later addition to the CSA or the regulations, but part and parcel of the original enactment. It is an "interpretive rule," which, rather than creating new duties, "simply states what the administrative agency thinks the statute means, and only reminds affected parties of existing duties. . . ." *Tennessee Hosp. Ass'n v. Azar*, 908 F.3d 1029, 1042 (6th Cir. 2018). The *Southwood Pharmaceutical* proceedings confirm this is so: if the duty had not already existed, Southwood would not have lost its registration for failing to comply with it.

DEA's construction – and that of the federal court – is plainly correct that *effective* control against diversion cannot be maintained if suspicious orders are shipped without investigation. Suspicious orders are, by definition, orders that that bear some indicia of diversion activity, including unusual size, unusual patterns, and/or unusual frequency. 21 C.F.R. § 1301.74(b). They are orders that raise sufficient concerns about diversion that they must be reported to the DEA. *Id.*; *see also* Bierstein Aff., Exhibit C ("The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders *when discovered* by the registrant.") (emphasis in original). It is therefore reasonable to conclude that shipping suspicious orders without further investigation will not be an effective means to prevent diversion. Indeed, the construction recognizes that the registrants are partners with the DEA in the prevention of diversion, and that reliance on the DEA alone to prevent diversion using the information reported to it will not be a system of effective controls. *See Southwood Pharmaceutical*, 72 FR 36487-01, 36504, 2007 WL 1886484.

That this construction of the CSA is correct has also been confirmed by Congress. On October 24, 2018, Congress enacted Public Law 115-271, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act"). Among other provisions, the SUPPORT Act amended 21 U.S.C. § 827 so as to provide manufacturers and distributors with access to data from the Automated Reports and Consolidated Orders System ("ARCOS"). *See* 21 U.S.C. § 827(f). As the SUPPORT Act explains, "The purpose of this chapter is to provide drug manufacturers and distributors with access to anonymized information through the

Automated Reports and Consolidated Orders System to help drug manufacturers and distributors identify, report, *and stop* suspicious orders of opioids and reduce diversion rates." PL 115-271, § 3272 (emphasis added). But the SUPPORT Act goes even further – the statute also provides a "Rule of Construction" explaining that "Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to— (1) identify, *stop*, and report suspicious orders; or (2) maintain effective controls against diversion. . . ." *Id.* (emphasis added).

Congress thus made crystal clear that the purpose of this particular provision of the SUPPORT Act is to give registrants additional tools – in the form of ARCOS data – to carry out their CSA duties, *including the duty to stop shipments*, and that the provision of these tools (or any previous lack of access to them) does not in any way absolve registrants of their statutory and regulatory duties, *including the existing duty to stop suspicious orders.*

In so doing, it is clear that Congress was aware of the DEA's construction of "effective controls against diversion" and intended to ratify it. "Subsequent legislation declaring the intent of an earlier statute is entitled to great weight in statutory construction." *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380-81, (1969). It is also significant that, in ratifying the DEA's construction of the CSA, Congress did not amend the CSA to impose more explicitly the no-shipping requirement. This court can reasonably infer that Congress did not expressly impose this duty because it understood that the duty *already* existed under the CSA, and that it was necessary only to make clear how the provisions of the SUPPORT Act might affect that duty. *See Heckler v. Turner*, 470 U.S. 184, 211 (1985) (clarification in subsequent legislation of existing statute not only "leaves no doubt as to the prospective interpretation of the statute, but it carries in addition considerable retrospective weight").

DEA's construction of the CSA and the regulations would, even without the confirmatory legislation, be entitled to substantial deference. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843-44 (1984) ("considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer'"); *People v. Newman*, 32 N.Y.2d 379, 388 (1973) ("The construction thus given to the legislation by the very agencies charged with its

administration, supervision and enforcement is entitled to considerable weight."). Congress left it to the DEA to determine what constitutes "effective control against diversion," and DEA has made a reasonable determination of what is required. Moreover, as the Second Circuit has explained, in assessing an agency construction, the court "need not conclude that the agency construction was the only one it permissibly could have adopted ... or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Mei Juan Zheng v. Holder*, 672 F.3d 178, 183 (2d Cir. 2012). Rather, it is sufficient that the interpretation is a reasonable one. *Id.*; *see also Catskill Mountains Chapter of Trout Unlimited, Inc. v. Envtl. Prot. Agency*, 846 F.3d 492, 507 (2d Cir. 2017) ("the question for the court is whether the agency's answer is based on a permissible construction of the statute"); *Newman*, 32 N.Y.2d at 389 ("the construction given statutes and regulations by the agency responsible for their administration, if not irrational or unreasonable, should be upheld."). Indeed, a court "may not disturb an agency rule unless it is arbitrary or capricious in substance, or manifestly contrary to the statute." *Mayo Found. for Med. Educ. & Research v. United States*, 562 U.S. 44, 53 (2011); *see also Kar Onn Lee v. Holder*, 701 F.3d 931, 936 (2d Cir. 2012) (court "must defer" to agency interpretation if it is reasonable).

Congress's 2018 recognition of the no-shipping requirement adds even greater force to the deference that would usually be accorded to an agency interpretation, and leaves no room for doubt that, as Judge Polster concluded, in order to carry out the statutory mandate to "maintain effective controls against diversion," a registrant may not ship suspicious orders that have not been cleared through investigation. It must, instead, block those orders until it can determine that diversion is unlikely.

B. New York's Controlled Substances Act Imposes the Same Requirement

The New York Controlled Substances Act ("NYCSA") is intended to be consistent with the federal CSA "to the fullest extent practicable." *Doe v. Axelrod*, 136 A.D.2d 410 (1st Dep't 1988). Under the NYCSA, an applicant for a license to manufacture or distribute controlled substances is required to demonstrate that it "is able to maintain effective control against the diversion of the controlled substances for which the license is sought." Pub. Health Law § 3312(c). Grant of the

license requires that the commissioner be satisfied that "the applicant will be able to maintain effective control against diversion of controlled substances." Pub. Health Law § 3313(a). Licensees must further "establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders." 10 N.Y.C.R.R. § 80.22. The definition of "suspicious orders" is identical to the definition found in the federal regulations discussed above. Licensees under the NYCSA are required to demonstrate compliance with the federal CSA, *see* Pub. Health Law § 3315(2)(iii) so that, in effect, the requirements of federal law are incorporated into the New York statute as well. For this reason, this Court can readily find that a violation of the federal "no-shipping" requirement also violates the NYCSA.

II. THE CSA REQUIRES PHARMACY CHAINS TO ENSURE THAT OPIOIDS ARE DISPENSED PURSUANT TO LEGITIMATE PRESCRIPTIONS AND NOT TO FILL PRESCRIPTIONS UNTIL RED FLAGS HAVE BEEN RESOLVED

The Pharmacy Chain Defendants engage in wholesale distribution of opioids and, in that capacity, their obligations are no different from that of any other wholesale distributor. As discussed above, this includes the duty not to ship suspicious orders until the distributor is able to determine that diversion is unlikely. This duty applies regardless of whether a distributor is shipping to a customer (pharmacy) with whom it has no corporate relationship or to a store that, as in the case of the Pharmacy Chain Defendants, is part of the same corporate family. But the Pharmacy Chain Defendants also dispense opioids at the retail level. In this capacity, they are subject to additional duties that require them to ensure that opioids are dispensed pursuant to legitimate prescriptions.

At the outset, it is important to note that the Pharmacy Chain Defendants before this Court are not the individual retail stores operated by each chain, but rather the parent corporation that owns the stores. Thus, CVS stores within New York are owned by CVS Albany, Inc. and CVS Pharmacy, Inc.; Walgreens stores are owned by Walgreen, Co.; Rite-Aid Stores are owned by Rite Aid of New York, Inc. The duties at issue here are the duties owed by these parent corporations, based on the dispensing activities of the stores they own.

A. The CSA Prohibits a Pharmacy from Dispensing Controlled Substances Other than Pursuant to a Valid Prescription Written for a Legitimate Medical Purpose

The CSA provides that, unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency. 21 U.S.C. § 829(a). Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b). The implementing regulations regarding dispensing of controlled substances specify that a valid controlled substance prescription may only be issued by an individual who is (a) "authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession" and (b) registered with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1306.03. Furthermore, under 21 C.F.R. § 1306.04(a), a prescription, whether written or oral, is legally valid under the CSA only if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice."[4] 21 C.F.R. § 1306.04(a). Moreover, "[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." 21 C.F.R. § 1306.04(a).

---

[4] The CSA also defines the term "valid prescription" to mean "a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner." 21 U.S.C. 829(e). The *legitimacy* or *validity* of a prescription is thus distinct from the question of its medical *necessity*. Plaintiffs have alleged that certain defendants made fraudulent misrepresentations and omissions that induced medical professionals to write opioid prescriptions they would not have written had they been properly informed of the true risks and benefits of opioids. Whether or not medically necessary, such a prescription might nonetheless be valid and legitimate if it was written by a properly-licensed doctor in the usual course of his or her professional practice and for a patient for whom the doctor had conducted at least one in-person medical evaluation. Recognizing this distinction, the Eleventh Circuit has found that a pharmacist can determine that a prescription is not issued for a legitimate medical purpose without "practice[ing] medicine or independently examin[ing] a patient." *Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 823, 832 (11th Cir. 2018); *see also United States v. Hayes*, 595 F.2d 258, 261 n.6 (5th Cir. 1979).

As a result, the "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a); United States Department of Justice, Drug Enforcement Administration Office of Diversion Control, *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* 29 (Rev. 2010). Thus, under the CSA, a pharmacy may not fill a controlled substance prescription unless it was issued for a legitimate medical purpose.

B. Pharmacies Are Obliged Not to Fill Prescriptions Until Red Flags Are Resolved

A pharmacy cannot ignore red flags indicative of diversion. On the contrary, "a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Medic-Aid Pharmacy*, 55 Fed.Reg. 30,043, 30,044, 1990 WL 328750 (Dep't of Justice July 24, 1990). "[W]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid actual knowledge of the real purpose of the prescriptions." *East Main Street Pharmacy*; Affirmance of Suspension Order, 75 FR 66149-01, 2010 WL 4218766 (Dep't of Justice Oct. 27, 2010). Thus, § 1306.064 requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse. *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730, 1990 WL 352775 (Dep't of Justice Feb. 9, 1990). "When [pharmacists'] suspicions are aroused as reasonable professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense." *Id.; see also Townwood Pharmacy*; 63 Fed. Reg. 8,477, 1998 WL 64863 (Dep't of Justice Feb. 19, 1998) (revocation of registration); *Grider Drug 1 & Grider Drug 2*; 77 FR 44070-01, 2012 WL 3027634 (Dep't of Justice July 26, 2012) (decision and order); *The Medicine Dropper*; 76 Fed. Reg. 20,039, 2011 WL 1343276 (Dep't of Justice April 11, 2011) (revocation of registration); *Medicine Shoppe-Jonesborough*; 73 FR 364-01, 2008 WL 34619 (Dep't of Justice Jan. 2, 2008) (revocation of registration); *Notice of United Prescriptions Services, Inc.*; 72 FR 50397-

01, 50407-8, 2007 WL 2455578 (Aug. 31, 2007) (revocation of registration).[5] While not dispositive, the DEA Administrator's interpretation of DEA's own regulations is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quotation omitted).

Courts, too, have recognized the obligation *not* to dispense until red flags are resolved. *See Medicine Shoppe-Jonesborough v. Drug Enforcement Administration*, 300 F. App'x 409 (6th Cir. 2008); *United States v. Henry*, 727 F.2d 1373, 1378-79 (5th Cir.1984); *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145 (D.D.C. 2012). In *Medicine Shoppe-Jonesborough,* the Sixth Circuit affirmed a pharmacy's liability for filling false or fraudulent prescriptions for controlled substances, concluding that the pharmacy violated § 829 of the CSA and 21 C.F.R. § 1306.04. The Court held that "[t]he CSA forbids a pharmacy to dispense a Schedule II, III, or IV controlled substance without a prescription, 21 U.S.C. § 829(a)-(b), which 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,' 21 C.F.R. § 1306.04(a)." *Id.* at 412 (emphasis added). "Medicine Shoppe fell asleep at the wheel" in honoring prescriptions that should have prompted further inquiry. *Id.* at 413. Prescriptions that "involved excessive" quantities of drugs and "remedies outside the prescriber's ordinary area of practice" "should have raised red flags at Medicine Shoppe." *Id.* "[B]y filling these prescriptions anyway. . . the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk." *Id.*

In this respect, the duty of a pharmacy is analogous to that of a manufacturer or distributor. Just as manufacturers and distributors may not ship suspicious orders without proper due diligence to

[5] The DEA has frequently met with industry representatives to discuss "red flags" of diversion and abuse. *See* Rannazzisi Decl. cited in *Holiday CVS, L.L.C. v. Holder*, 839 F.Supp.2d 145 (D.D.C. 2012), Case No. 1:12-cv-00191-RBW, Dkt. 19, Ex. 6 (Bierstein Aff., Exhibit D). According to DEA, pharmacists are the "[l]ast line of defense." *See e.g.* Birmingham Pharmacy Diversion Awareness Conference, *DEA Perspective: Pharmaceutical Use & Abuse* (Mar. 28-29, 2015) at 139-40 (Bierstein Aff., Exhibit E).

determine that diversion is not likely, so, too, pharmacies may not fill prescriptions in the presence of unresolved red flags about the legitimacy of the prescription or the prescriber.

C. The Pharmacy Chains Are Responsible for the Dispensing Practices in Their Stores

The responsibility for dispensing is not limited to pharmacists, pharmacies, or holders of DEA dispensing registrations. Rather, the corporate parent of a pharmacy may be responsible for the dispensing practices of its pharmacies and pharmacists. *See United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2016 WL 9045859, (N.D. W.Va. Dec. 19, 2016); *United States v. Stidham*, 938 F.Supp. 808, 814 (S.D.Ala.1996); *United States v. Poulin*, 926 F.Supp. 246, 250, 253 (D.Mass.1996); *United States v. Robinson,* No. 12-20319-CIV, 2012 WL 3984786, (S.D. Fla. Sept. 11, 2012). This is so regardless of whether the parent is a registrant under the CSA or whether the parent is the entity or person actually doing the dispensing.

1. The CSA Applies to All Persons Who Dispense Controlled Substances

The CSA provides that it is "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized. 21 U.S.C. § 841(a)(1). The CSA further provides that "[i]t shall be unlawful for any person – (1) who is subject to the requirements of part C [setting forth registration requirements] to distribute or dispense a controlled substances in violation of section 829 of this title." 21 U.S.C. § 842(a)(1). By its terms, § 841 applies to all "persons," and the Supreme Court has held that DEA registrants and non-registrants alike can be held responsible for violations of § 841. *See United States v. Moore*, 423 U.S. 122, 131 (1975). Courts have similarly held that § 842(a) is not limited to registrants. *See United States v. Blanton*, 730 F.2d 1425, 1434 (11th Cir.1984) (holding that Section 842(a)(5) applied to a physician who was not properly registered with the DEA); *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 313–14 (E.D.La.1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991) ("Had Congress intended to limit the applicability of § 842(a)(5) to registrants only, it would have done so"); *United States v. Stidham*, 938 F.Supp. at 814; *United States v. Poulin*, 926 F.Supp. at 246.

2. The Owner of a Pharmacy Need Not Be a Registrant to Violate the CSA

Courts have interpreted the CSA and its implementing regulations to impose liability on those persons or entities who were ultimately responsible for the dispensing violations, regardless of whether the responsible party is a registrant and regardless of attempts to use corporate formalities to insulate from liability. In *City Pharmacy*, the court found that the owner of the pharmacy could be held liable in his personal capacity for violations of § 842(a)(1) even though he was not a registrant and the pharmacies he owned were separately incorporated. 2016 WL 9045859, **2-4. There, the government brought an action alleging that City Pharmacy LLC and City Pharmacy of Charles Town, Inc. violated 21 U.S.C. § 842(a)(1) by filling illegitimate prescriptions for controlled substances, "including those which were: (1) written by medical providers located in distant states; (2) presented by individuals who traveled from distant locations;(3) paid for using cash; (4) altered by scratching out the medical provider's fill date, increasing the number of units being prescribed or changing the strength, nature or type of controlled substance; and (5) lacking the full name or address of the patient for whom the prescription was written." *Id.* at *2. The government's complaint named as defendants the corporate pharmacy entities (City Pharmacy LLC and City Pharmacy of Charles Town, Inc.) as well as the individual owners of the corporate entities in their personal capacities. The individual defendant's involvement with the pharmacies included investing the funds to organize and open the pharmacies, overseeing the finances of the pharmacies, managing personnel, delivering prescriptions to customers, and being was actively involved in the management of the pharmacies.

The individual pharmacy owner defendant argued that he could not be held liable for the pharmacies' violation of § 842 because he was not a pharmacist, he was not filling prescriptions at either pharmacy location, and his role in the operation of CP and CPCT was "limited." The court rejected his arguments, explicitly holding that "§ 842(a)(1) applies to non-registrants, like defendant Lewis." 2016 WL 9045859 at *2 (citing *Moore*, 423 U.S. at 134 n.11 and *Stidham*, 938 F.Supp. at 813-814). The Court continued: "[B]ecause part C of the CSA applies broadly to all persons involved in the manufacture, distribution, and dispensing of controlled substances, including lay-persons, defendant Lewis may potentially be held liable for his conduct." *Id.* To support its conclusion, the

Court concentrated on the defendant's involvement with the pharmacies at issue, looking specifically at his investment of the funds to organize and open the pharmacy, the active role he played in the management of the pharmacies including overseeing the finances of the pharmacies, managing personnel, and delivering prescriptions to customers.

The *City Pharmacy* court also found that the individual defendant could not use the pharmacies' separate incorporation to shield himself from CSA liability. Looking towards various legal mechanisms for piercing the corporate form, the court concluded that the pharmacies "were being used to evade the legal requirements within and undermine the public policy foundations of the CSA." 2016 WL 9045859, at *4. Thus, the Court held that, "given the nature of these criminally-grounded allegations, it is not a defense to liability in this case for defendant Lewis to assert that he is shielded by the corporate form. [The pharmacies] were allegedly the entities used to evade and subvert the requirements of the CSA." *Id.* Other courts have similarly held that non-registrant pharmacy owners who operate pharmacies on a day-to-day basis must comply with the CSA. *See Poulin*, 926 F.Supp. at 249 *("*Mattapoisett Pharmacy, Inc. is also the alter ego of its sole owner, David Poulin, and thus David Poulin cannot use the corporate name to shield himself from personal liability."); *Robinson,* 2012 WL 3984786 (non-registrant pharmacy owner liable for pharmacy violations of 21 U.S.C. § 842.); *see also S & S Pharmacy*; 46 Fed. Reg. 46 FR 13051-03, 1981 WL 96125 (Dep't of Justice Feb. 19, 1981) ("[T]he Administrator has in the past looked behind the corporate-veil to revoke or deny a registration when a responsible official of a corporate registrant has been convicted of violating the laws relating to controlled substances."). Thus, in *Robinson*, the court rejected Defendant's argument that she was merely a corporate representative. The court held that "[w]here corporate officers have been in a position to prevent or correct the violations at issue, courts have found that there is individual liability under the subsection, which plainly applies to all 'persons.'" 21 U.S.C. § 842(a)(5). *Robinson,* 2012 WL 3984786 at *7; s*ee also United States v. Ahmad,* No. 4:15CV-181-JM, 2016 WL 11645908, at *3 (E.D. Ark. May 2, 2016), *aff'd sub nom. United States v. United Pain Care, Ltd.,* 747 F. App'x 439 (8th Cir. 2019) (finding an owner receiving the "benefits and profit" of a pharmacy, but who was not a registrant or

a medical professional, liable for violations of the CSA because he was still "responsible for making sure that [CSA] requirements were met.").

The logic of these cases is consistent with the purpose and intent of the CSA. The Supreme Court explained that with the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels." *Moore,* 423 U.S. at 135. So, to address this concern, courts are wary about using the DEA registration process and requirements, i.e. the structure of the legitimate channels, to somehow shield those responsible from liability. As one court put it, "[t]o accept [defendant's] argument that the Act does not apply to her [because she was not a registrant], even though she was responsible for the drugs, would eviscerate the goal of ensuring the movement of drugs is closely controlled." *Robinson,* 2012 WL 3984786 at *7. "The legislative history [of the CSA] indicates that Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant." *United States v. Moore,* 423 U.S. at 134.

The DEA made a similar finding in *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 Decision and Order*, 77 FR 62316-01, 62321-2; 2012 WL 4832770 (D.E.A. Oct. 12, 2012). The Administrative Law Judge rejected CVS's argument that the corporate parent of a chain pharmacy was not responsible for the actions of its pharmacies. In its analysis of whether or not CVS took responsibility for its actions, the ALJ held that:

> [T]he Agency's rule is clear and the fact that CVS is a large corporation provides no reason to excuse it from explicitly acknowledging the misconduct of Respondents and their pharmacists. Therefore, I decline to create one rule for chain pharmacies and another rule for closely held or sole proprietor owned pharmacies. Because Respondents have failed to satisfy this requirement, the ALJ properly held that they have not accepted responsibility for their misconduct.

At the most fundamental level, the purpose of the CSA and CSA regulations is to create a closed system for delivery of controlled substances and prevent the distribution of controlled substances outside of that system. To allow the entity that fully controls the operations of the registrants to escape responsibility because of corporate structure would defeat the purpose and intent of the CSA.

3. The Pharmacy Chain Defendants Cannot Escape Liability for Their Corporate Malfeasance by Blaming the Pharmacists Who Work for Them

Nor may Defendants escape liability by blaming their pharmacists. Even though the CSA speaks in terms of what a pharmacist – not a pharmacy – must do, courts have found that a narrow reading of the language to insulate pharmacies from liability is not supported by the language or structure of the regulations. For example, in *United States v. Appalachian Reg'l Healthcare, Inc.,* 246 F. Supp. 3d 1184, 1186 (E.D. Ky. 2017), the court looked at the regulations regarding dispensing under § 842 finding that the pharmacy owner could be held personally liable for dispensing violations. Appalachian Regional Healthcare (ARH) was a healthcare system in Eastern Kentucky that operated medical centers, hospitals, clinics, and several pharmacies affiliated with those facilities. The DEA charged ARH with violations of 21 U.S.C. § 842(a)(1) for filling false or fraudulent prescriptions and also for violations of 21 U.S.C. § 842(a)(5) for failing to make and maintain complete and accurate records.

ARH argued that it could not be held liable as a corporate pharmacy under § 842(a)(1) because the implementing regulation articulated the duties under that section in terms of the "pharmacist" or "practitioner," not the corporate pharmacy entity. *See* 21 C.F.R. § 1306.04(a) ("The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.").

The Court rejected the Defendant's narrow, technical reading, instead holding that "when § 1306.04(a) states that the person knowingly filling the prescription is subject to penalties, it contemplates liability for corporate entities as well." *Appalachian Reg'l Healthcare*, 246 F. Supp. 3d at 1189. The court continued, finding that there is "nothing inconsistent about articulating the responsibilities of individual practitioners and pharmacists while simultaneously indicating that other entities may be subject to penalties for their role in issuing and filling invalid prescriptions." *Id.* at 1189-1190.

Other federal courts have similarly found pharmacies liable for dispensing violations under the CSA and its regulations. In the *Medicine Shoppe* case, for example, the Sixth Circuit made no

distinction between the pharmacy and the pharmacists employed there when determining liability. *See* 300 Fed. App'x 409; *see also Jones Total Health Care Pharmacy LLC and SND Health Care LLC v. Drug Enforcement Administration*, 881 F.3d 823 (11th Cir. 2018) (affirming revocation of pharmacy registration for, among other things, pharmacists dispensing prescriptions that prescriptions presented various red flags, *i.e.*, indicia that the prescriptions were not issued for a legitimate medical purpose without resolving red flags); *United States v. Green Drugs*, 905 F.2d 694, 694-5 (3rd Cir. 1990) (affirming retail pharmacy liability for violating § 842(a)); *United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-23 (5th Cir. 1991) (affirming liability under § 842(a) for corporate operator of clinic that illegally distributed controlled substances); *United States v. Cap Quality Care, Inc.*, 486 F. Supp. 2d 47, 54 (D. Maine 2007) (granting summary judgment to the United States on claims that DEA registrant clinic improperly dispensed controlled substances in violation of § 829 and § 842); *United States v. Grab Bag Distrib.*, 189 F. Supp. 2d 1072, 1082 (E.D. Cal. 2002) (granting summary judgment to the United States on liability); *United States v. Little*, 59 F. Supp. 2d 177, 186-8 (D. Mass. 1999) (granting summary judgment to Government for pharmacy's violations of § 842(a) and concluding "a pharmacy empowered to dispense controlled substances will now be held liable . . . if it knew or should have known about an illegal diversion, or inaccurate records, and chose to do nothing"); *Poulin*, 926 F. Supp. at 252-3 (holding pharmacy liable for "filling a total of six invalid prescriptions"); *United States v. Queen Village Pharm.*, No. 89-2778, 1990 WL 165907, *2-4 (E.D. Pa. Oct. 25, 1990) (finding retail pharmacy liable for violating § 842(a)).

These decisions make clear that the dispensing obligations under the CSA are not imposed solely on pharmacists, but on pharmacies and their corporate owners. For this reason, this Court should find that the Chain Pharmacies had a responsibility, under the CSA, not to dispense opioids in the face of unresolved red flags about the legitimacy of the prescriptions.

CONCLUSION

For the foregoing reasons, this Court should rule that (1) the CSA imposes an obligation to maintain effective controls against diversion, and that in order to meet this obligation, manufacturers and distributors of controlled substances must design and operate a system to identify suspicious

orders; must report suspicious order to the DEA; and must stop shipment of suspicious orders pending investigation and due diligence; and (2) the CSA imposes obligations to dispense opioids only pursuant to a valid, medically legitimate prescription and not to dispense in the face of unresolved red flags, and these obligations are imposed not only on individual pharmacists, but also on pharmacies and the corporate parents who control them.

Dated: January 14, 2020

Respectfully submitted,

/s/ Andrea Bierstein
Paul J. Hanly, Jr.
Jayne Conroy
Andrea Bierstein
Sarah S. Burns (pro hac vice)
Richard Kroeger (pro hac vice)
SIMMONS HANLY CONROY LLC
112 Madison Avenue
New York, NY 10016
(212) 784-6401
phanly@simmonsfirm.com
jconroy@simmonsfirm.com
abierstein@simmonsfirm.com
tsheridan@simmonsfirm.com
sburns@simmonsfirm.com
rkroeger@simmonsfirm.com

and

/s/ Paul J. Napoli
Paul J. Napoli
Salvatore C. Badala
Joseph L. Ciaccio
NAPOLI SHKOLNIK PLLC
400 Broadhollow Road, Suite 305
Melville, New York 11747
(212) 397-1000
Fax: (646) 843-7603
pnapoli@napolilaw.com
sbadala@napolilaw.com
jciaccio@napolilaw.com

Plaintiffs' Co-Lead Counsel

and

LETITIA JAMES
Attorney General of the State of New York

By: /s/ David E. Nachman
David E. Nachman, Counsel for Opioids and Impact Litigation
Lawrence Reina, Assistant Attorney General
Carol Hunt, Assistant Attorney General
Elizabeth Chesler, Assistant Attorney General
Office of the New York State Attorney General
28 Liberty Street
New York, New York 10005
(212) 416-6305
David.Nachman@ag.ny.gov
Lawrence.Reina@ag.ny.gov
Carol.Hunt@ag.ny.gov
Elizabeth.Chesler@ag.ny.gov